IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Hans Josef Stauss and Liquan Gao		
Serial No.:	09/625,963	Art Unit:	1644
Filed:	July 26, 2000	Examiner:	Francois Vandervegt
For:	*IMMUNOTHERAPEUTIC METHODS USING EPITOPES OF WT-1 AND GATA-1*		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

We, Hans Josef Stauss and Liquan Gao, hereby declare that:

1. We are co-inventors of the claimed subject matter.

2. We are familiar with the office action mailed November 3, 2004 in which claims 1, 5, 7, 15, and 19 were finally rejected under 35 U.S.C. § 102 (e) as being anticipated by U.S. Patent Application Publication 20030082196 by Gaiger, et al., published on May 1, 2003, which claims priority to U.S. Serial no. 09/164,223 filed September 30, 1998. We are familiar with the U.S. Patent Application Publication 20030082196 by Gaiger, et al. that discloses peptides containing the amino acid sequence RMFPNAPYL (SEQ ID NO: 2 (human), SEQ ID NO: 185 (human), SEQ ID NO. 3 (mouse) and SEQ ID NO:293 (mouse)) at least at page 1 paragraph 0008 and at page 6 paragraph 0053.

DECLARATION UNDER 37 C.F.R. § 1.131

3. We conceived and reduced to practice the peptide containing the amino acid sequence RMFPNAPYL as defined by claims 1, 5, 7, 15, and 19 as currently pending in the above-identified patent application, prior to September 30, 1998 as demonstrated by the attached copies of pages from our laboratory notebooks (Exhibit B). This work was performed in our laboratory in London, United Kingdom.

4. The amino acid sequence of human WT-1 was manually scanned to identify candidate peptides (listed in Exhibit A) that had predicted HLA-A2 anchor residues. These candidate peptides were chemically synthesized and used for binding and cytotoxic T-cell (CTL) induction assays.

5. The peptide containing the amino acid sequence RMFPNAPYL, represented as huWT 126-34 in Exhibit A and as WT-1/126 in Exhibit B, bound to HLA-A0201, represented as HLA-A2 in Exhibit B, on T2 cells (Exhibit B, page 3). This demonstrates that we were in possession of peptides containing the amino acid sequence RMFPNAPYL and that the peptide binds to HLA-A0201-positive antigen presenting cells (APC). As noted in Exhibit B, pages 7-8, cytotoxic T-cells (CTL) kill T2 target cells incubated with WT-1/126 peptide. This demonstrates that the peptide is capable of eliciting a CTL response. As noted in Exhibit B, page 10, cytotoxic T-cells (CTL) incubated with WT-1/126 peptide kill target cells endogenously expressing WT-1. This demonstrates that the peptide is capable of eliciting a CTL response against cells expressing the WT-1 protein. As noted in Exhibit B, pages 11-12, cytotoxic T-cells (CTL) incubated with WT-1/126 kill CD34+ chronic myelogenous leukemia (CML) cells. The specification at least at page 8, lines 26-27, discloses that leukemias over-

express WT-1. This demonstrates that the peptide is capable of eliciting a CTL response against tumor cells expressing HLA-A0201 and over-expressing WT-1.

6. In summary, as demonstrated by this data, we conceived and reduced to practice the peptide containing the amino acid sequence RMFPNAPYL as defined by claims 1, 5, 7, 15, and 19 of the above-identified patent application prior to September 30, 1998.

7. I declare that all statements made herein of my own knowledge and belief are true and that all statements made on information and belief are believed to be true, and further, that the statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 7-3-06

Hans Josef Stauss

Date: 7-3-06

Liquan Gao

Peptides ordered

HLA0201 motifs:
huWT 10-18: ALLPAVPSL
huWT 17-26: SLGGGGGCAL
huWT 126-34: RMFPNAPYL
huWT 187-95: SLGHQQYSV
huWT 225-33: NLYQMTSQL
huWT 235-43: CMTWNQMNL
huWT 280-88: ILCGAQYRI
huWT 441-49: NMTKLQLAL

huIK103-12: ALSGVGGIRL
huIK116-24: KLKCDICGI
huIK231-39: GLPGTLYPV
huIK231-40 GLPGTLYPVI
huIK321-30: YLGAESLRPL
huIK373-81: LLLLSKAKL
huIK374-82 LLLSKAKLV
huIK410-18: GLIYLTNHI
huIK471-79: FLDHVMYTI

K^b motifs:
muWT 45-52: GASAYGSL
muWT 145-52: RNQGYSTV
muWT 290-97: THGVFRGI
muWT 330-37: CNKRYFKL

muG74-81: VFQVYPLL
muG227-34: ACGLYHKM
muG281-88: ACGLYFKL
muG330-37: PAGGFMVV
muG357-64: TAHLYQGL

D^b motifs:
muWT 221-29: YSSDNLYQM
muWT 126-34: RMFPNAPYL
muWT 235-43: CMTWNQMNL
muWT 437-45: MHQRNMTKL

muG234-42: MNGQNRPLI
muG125-33: EGKSNNTFL
muG222-30: HYLCNACGL
muG276-84: DPVCNACGL